K004005 (R2 OF 2)

OCT 1 2 2001

510(k) SUMMARY

Date: December 22, 2000

Submitter: Donna A. Crawford
Director, Corporate Regulatory Affairs
Mentor Corporation
201 Mentor Drive
Santa Barbara, CA 93111
Phone: 805-879-6304
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Trade or Proprietary Name: Mentor® Contour Genesis System

Common or usual name: Ultrasound-assisted lipoplasty system

Description and Intended Use of Device:

The Mentor Contour Genesis System consists of the following components: ultrasonic generator, infiltrator, aspirator, ultrasonic handpiece, foot pedal(s), cannulae and cannulae sheaths, system cart, irrigation tubing set, infiltration tubing set, and aspiration tubing set.

The Mentor Contour Genesis System is indicated for the liquefication and aspiration of soft tissues in General Surgery, Plastic and Reconstructive Surgery and Gynecological Surgery applications. It is also indicated for the liquefication and aspiration of localized subcutaneous fatty deposits for the purposes of aesthetic body contouring.

Substantial Equivalence:

The Mentor Contour Genesis System is substantially equivalent to the Mentor Ultrasound-Assisted Tissue Removal System which was cleared under 510(k) K970471 for the liquefication and aspiration of soft tissues in General Surgery, Plastic and Reconstructive Surgery and Gynecological Surgery applications.

The primary difference is that the Contour Genesis System is also indicated for the liquefication and aspiration of subcutaneous fatty deposits for the purposes of aesthetic body contouring.

A clinical study was conducted to compare ultrasound-assisted lipoplasty (UAL) to suction-assisted lipoplasty (SAL). A total of 366 subjects were enrolled in the study; of these, 180 were UAL patients and 186 were SAL patients. For the primary safety

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measures, the proportions of subjects reporting any adverse event were similar between the two treatments (18.8% for UAL and 19.9% for SAL). The statistical analysis indicated that the proportion in the UAL group was equivalent to that in the SAL group. For the secondary effectiveness measures, subjects in the UAL group reported an overall satisfaction rate of 90.3%, compared with 95.2% in the SAL group. Subjects in the UAL group had a statistically significant improvement in their feelings towards each body area treated, a statistically significant improvement in self-esteem as measured by the Rosenberg Self-Esteem scale and the Body Esteem scale, and a statistically significant improvement in body contour measurements as assessed by a masked reviewer. Very few differences were seen between UAL and SAL in these effectiveness measures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 2 2001

Ms. Donna A. Crawford
Director, Corporate Regulatory Affairs
Mentor Corporation
201 Mentor Drive
Santa Barbara, California 93111

Re: K004005
Trade/Device Name: Mentor® Contour Genesis System
Regulation Number: 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: II
Product Code: MUU
Dated: July 17, 2001
Received: July 17, 2001

Dear Ms. Crawford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walker, MD

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(K) Number : K004005

Device Name:

Mentor® Contour Genesis System

Indications for Use:

The Mentor Contour Genesis System is indicated for the liquefication and aspiration of soft tissues in General Surgery, Plastic and Reconstructive Surgery and Gynecological Surgery applications. It is also indicated for the liquefication and aspiration of localized subcutaneous fatty deposits for the purposes of aesthetic body contouring.

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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